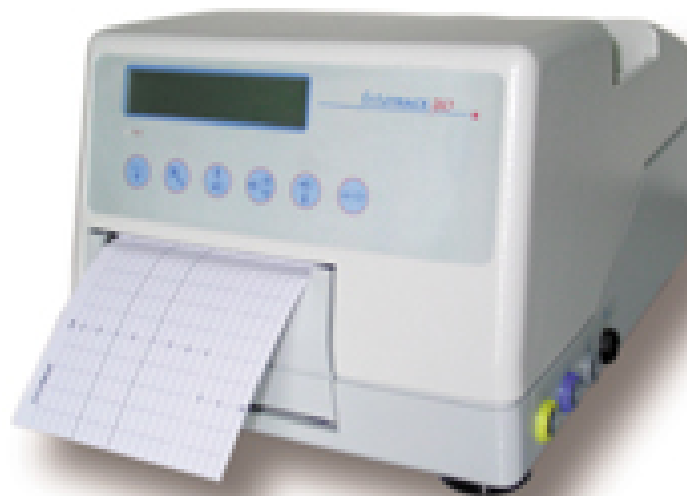




# ***Operating Manual Fetatrack 310 Fetal Monitor***







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## ***About This Manual***

This booklet explains the operation and use of the *FETATRACK 310 Antenatal Cardiotocograph*. Care has been taken during the design and manufacture of this product so that it satisfies all of the current safety standards set down by BS EN60601-1-1990.

To achieve the best from this product read the following sections several times and if you have any problems in the operation of a particular part of the product then contact your dealer immediately or contact :

Ultrasound Technologies Ltd  
Lodge Way  
Portskewett  
Caldicot, NP26 5PS  
South Wales  
UK  
Tel +44 (0) 1291 425425  
Fax +44 (0) 1291 427093  
EMAIL [service@doppler.co.uk](mailto:service@doppler.co.uk)

A service manual containing circuit descriptions, diagrams, parts and spares lists is available for the *FETATRACK 310* by contacting the address above.

To maintain the *FETATRACK 310*'s performance it is recommended that it be included in a periodic maintenance program. The user preventative maintenance program is covered in this manual. Maintenance outside the scope of the user should be undertaken on an annual basis by trained service personnel; full details are available from your supplier, service centre or from Ultrasound Technologies Ltd.

The FETATRACK 310 is supplied complete with the following: -

|                            |                           |
|----------------------------|---------------------------|
| FETATRACK 310 Single Fetus | FETATRACK 310 Twin Fetus  |
| Monitor                    | Monitor                   |
| US1 Monitoring Transducer  | US1 Monitoring Transducer |
| External Toco Transducer   | US2 Monitoring Transducer |
| Patient Event Marker       | External Toco Transducer  |
| Belt and Buckle set (x2)   | Patient Event Marker      |
| Chart pack (x1)            | Belt and Buckle set (x3)  |
| Power Cord                 | Chart pack (x1)           |
| Operating instructions     | Power Cord                |
| Coupling gel (0.25ltr)     | Operating instructions    |
|                            | Coupling gel (0.25ltr)    |





## *Safety In Use*

### Special Precautions

Your *FETATRACK 310 Antenatal Cardiotocograph* has been designed for electrical safety. All the safety and operating instructions should be read before operating the *FETATRACK 310*. Failure to do so could result in injury to the user, patient, or damage to the system and accessories.

### Electrical Shock Hazard

Do not defeat the grounding integrity of this system. Protection against electrical shock, in the event of failure of basic insulation, is provided by the connection of the chassis to the safety ground. Safety grounding occurs only when the 3-wire cable and plug provided with the system are connected to a properly grounded receptacle.

Do not remove the system cover. The system should be serviced by trained and qualified personnel only. Contacting the hazardous voltages within the system could cause serious injury.

Do not use the system if the power cord has any cuts or openings.

Do not use the transducer if the cable has any cuts or openings.

Do not use the transducer if the transducer face is cracked or chipped.

Do not immerse the transducer cable connectors in any liquids.

Should the electrical safety fuses have to be replaced, use only fuses of the same type and rating.

### Explosion Hazard

Do not operate or use this system in the presence of flammable anesthetics or gases as it could lead to explosion.



## Handling the Delicate Transducers

The transducers are delicate parts of the ultrasound system and should be treated with care. The delicate crystals in the transducer may crack and render the transducer unusable if the transducer is subject to shock. Room temperature liquids should be used for cleaning.

**NEVER** use alcohol or mineral oil as an acoustic coupling agent as transducer face and cable damage will occur.

**ONLY** use approved ultrasound coupling gels.

## Symbols Used

The following symbols are used on the *FETATRACK 310* and are in accordance with BS EN60601-1-1990.

Where they are associated with the connection of external equipment, that equipment **must meet** the relevant safety standards in all cases.



Alternating current  
Associated with power on indicator



Type B Equipment  
Unit classification



Off (power: disconnection from the mains)



On (power: connection to the mains)



Attention, consult accompanying documents.  
Associated with auxiliary connections see  
operating instructions.



This symbol on the product or on its packaging indicates that this product must not be disposed of with your normal waste.

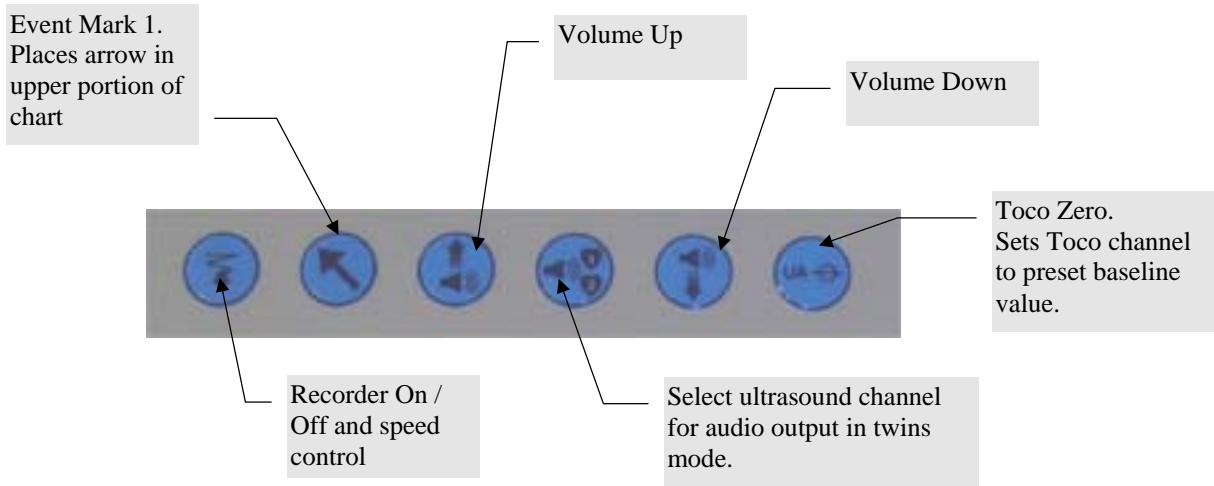




## ***Parts and Their Functions***

### **FETATRACK 310 Front Panel Controls**

The front panel control area contains 6 buttons used to control the operation of the unit, they are all indicated by icons to aid language variations.



#### **Recorder On/Off and Speed Change**

This button is used to control the operation of the recorder. Press once and the chart recorder will start, each consecutive short press will change the speed. Pressing and holding the button down will stop the recording.

#### **Event Mark 1**

Places an event mark arrow at the top of the FHR scale.

#### **Volume Up**

This button is used to increase the audio volume level, or in configuration mode to change user options.

#### **Volume Down**

This button is used to decrease the audio volume level, or in configuration mode to change user operations.

#### **US1 / US2 Transducer Select in Twins mode**

Pressing this button changes the selected probe from US1 to US2 for volume output. This is used when the unit is in twins mode with two US channels for listening to either of the two fetuses. Press and hold to activate twins trace offset.

#### **Toco Zero**

This button zeros the Toco trace to the selected baseline.





## *Parts and Their Functions*

### **Inputs / Outputs and Displays**

#### **'Power On' Indication**

The green LED associated with the above symbol indicates that power is connected to the apparatus when illuminated.

#### **RS232 Output**

This output is for the connection of an external computer for data transfer. The maximum voltage that can be applied to this output is 15VDC.

**WARNING:** Any external equipment connected to this output must meet the equivalent **MEDICAL** safety standard to this product. Connection must only be made by a qualified technician. An isolation connection may be necessary when connection is to be made to a personal computer.

#### **Remote Event Marker**

Connection of an external event mark switch allows the patient to indicate events by printing an arrow in the gap between the FHR and UA traces. The maximum voltage that can be applied to this output is 15VDC.

#### **Probe Connections US1, US2, Toco**

This is for the connection of approved Doppler and Toco transducers. The maximum voltage that can be applied to this output is 15VDC.






## ***Operating Procedures***

### Operating the *FETATRACK 310*

In this section, information is supplied which will help you use the *FETATRACK 310* for the first time.

#### *User Configuration*

Firstly connect the *AC supply cord*.

It is necessary to set the operation of the *FETATRACK 310* to meet your requirements. Before turning the *FETATRACK 310* on, press and hold down the *Toco Zero* button. Then, whilst keeping the *Toco Zero* button pressed down, turn the *FETATRACK 310* on by flicking the *AC input on/off* switch which is located on the rear of the unit as part of the *AC line input socket*. When the unit is on the front panel LED  will be illuminated.

The *FETATRACK 310* starts and then enters its *User Configuration Mode*, release the *Toco Zero* button as soon as '*Calibrate System*' is displayed .

You are then prompted to enter the date if different to that displayed. To change the day and month press the *Volume Up* button. One press advances the day by one, pressing the *Volume Up* button for longer advances the day by 10.

To change the year press the *Volume Down* button. One press advances the year by one, pressing the *Volume Down* button for longer advances the year by 10.

When the correct date is displayed press the *Toco Zero* button once.

You are then prompted to enter the time if different to that displayed. This works in a similar manner to the date with the *Volume Up* button advancing the hours and the *Volume Down* button advancing the minutes.

When the correct time is displayed press the *Toco Zero* button once.

You are then prompted to enter the *Toco Base Line* offset. This sets an artificial zero line for the *toco* transducer above zero, it can be set by pressing the *Volume Up* or *Volume Down* buttons for a value between 0 - 20. After setting this value the *Toco* will be set to this every time the *Toco Zero* switch is pressed, and allows small negative *Toco* excursions to be seen on the chart.

When the chosen zero offset is displayed press the *Toco Zero* button once.





## *Operating Procedures*

You are then prompted to enter the Toco Filter Value.

This sets the filtering within the monitor to produce a smoother Toco trace if required. ( The filter can remove some of the maternal breathing artifact). It is set by pressing the *Volume Up* button for a value soothing value between 1sec and 2sec..

When the correct filter value is displayed press the *Toco Zero* button once.

You are then prompted to enter the Toco Range.

This sets the response of the Toco transducer to either a full scale of 100 or 200 on the chart print out. It is set by pressing the *Volume Up* button for a value between 100 and 200..

When the correct range is displayed press the *Toco Zero* button once.

You are then prompted to enter the Chart recorder speed.

This sets the initial turn-on speed of the chart recorder. Then once the chart is running the speed can be further changed to 1, 2 or 3 cm/min. It is set by pressing the *Volume Up* button for a value of 1, 2 or 3 cm/min..

When the correct speed is displayed press the *Toco Zero* button once.

You are then prompted to select the Data Block on or off.

The Data Block is printed at the start of each recording, this function can be disabled by setting Data Block to off. It changes from on to off and back again by pressing the *Volume Up* button..

When the Data Block is set to your requirements press the *Toco Zero* button once.

You are then prompted to select the Tachycardia Alarm on or off.

The Tachycardia Alarm is triggered when the system detects a Tachycardia above a preset value that the user can choose. The Alarm can be a level alarm or one calculated from a complex. Press the *Volume Up* button to change the setting. The alarm is tone is silenced by pressing the units *Volume* button.

When the Tachycardia Alarm is set to your requirements press the *Toco Zero* button once.

You are then prompted to select the Bradycardia Alarm on or off.

The Bradycardia Alarm is triggered when the system detects a Bradycardia below a preset value that the user can choose. The Alarm can be a level alarm or one calculated from a complex. Press the *Volume Up* button to change the setting. The alarm is tone is silenced by pressing the units *Volume* button.

When the Bradycardia Alarm is set to your requirements press the *Toco Zero* button once.

The *FETATRACK 310* will then restart and operate according to your settings.

The *FETATRACK 310* is now operational, and the LCD screen will show US1 --- us2 --  
-

(if the unit is only a single fetus monitor it will only display US1 ---) and a Toco value.



## ***Operating Procedures***

### **The Printer**

The FETATRACK 310 prints on preprinted z-fold thermal paper using a thermal array print head. Fetal heart rate, uterine activity, and fetal movement are recorded together with date, time, recorder speed, operating mode and alarm status. The printer also prints a header block each time the printer is turned on, that contains Time and Date, Patient Name, Gestational Age, Patient or Bed Number, Hospital or Doctor along with a print viability test bar that prints to all dots of the printhead.

To load the printer with paper, open the printer door by pulling the recorder door using the opening provided on the printer. It will then release and opens downwards exposing the printer paper tray. Remove the new paper pack from its protective plastic cover and insert the pack into the recorder so that the printed side of the paper is uppermost and the FHR trace is on the left.



Pull the paper out of the front of the unit making sure it is positioned parallel to the roller and then close the door. The pack will self align when the recorder is run.

To operate the printer press the Recorder On/Off button. The printer will start to run and the chart speed will be shown in the LCD display. To turn the printer off press and hold the Recorder On/Off button until the printer stops. (This only operates after the data block has been printed). A small amount of paper will be fed out at high speed.

The printer will record at 1, 2 or 3 cm/min. To change the speed during recording simply press the Recorder On/Off button momentarily. The FETATRACK 310 can be run at the speed of your choice, and will always start at this pre-programmed speed every time the printer is turned on. For details of how to change the pre-programmed speed refer to 'User Configuration'.

When the paper pack runs out the Fetatrack 310 will sound a short alarm and display "Paper ?". For the next 30 min the system will store HR1, HR2 and Toco until either the store becomes full, the user presses and holds the Recorder On/Off button to reset the store and lose the stored data or the user inserts a new paper pack, presses Recorder On/Off button once and the Fetatrack 310 prints the stored data and returns to normal printing.

When the store reaches 90% full the Fetatrack 310 will "Alarm" and show "StoreLow", if the store then becomes full the display changes to "StoreFull" and there will be no further storage. The data can still be printed by pressing Recorder On/Off button once or reset by pressing and holding the Recorder On/Off button.

The print from store is lighter than the normal trace to distinguish stored data.





## ***Operating Procedures***

### Ultrasound Fetal Monitoring

The *FETATRACK 310* ultrasound transducer is used to detect and monitor the fetal heart beat. The *FETATRACK 310* can monitor twins and if this option is chosen it is supplied with two Ultrasound transducers. The primary Ultrasound Transducer (always supplied ) has a yellow coded plug while the twin channel has a blue coded plug. Push the relevant plug firmly into its colour coded front panel US socket and turn the unit on.

Locate a clear fetal heart sound using a Doppler Fetal Heart Detector and secure the stretch belt in position, so that it passes over the transducer site, and clamp in place by fastening the buckle after feeding the belt through the transducer.

Apply gel to the surface of the transducer locating it approximately in the position determined by the Doppler detector. Position the transducer to obtain the clearest fetal heart sound. The heart rate processor will start to calculate heart rate within a few seconds and the heart rate can be observed on the LCD display. Correct operation can be verified by observing that the pulse lamp is flashing at the heart rate.

The heart shaped fetal pulse indicator is also used as a signal quality indicator. When positioning the transducer observe the indicator, which should be solid under the best signal conditions. If this indicator is only showing an outline heart then this is an indication that the signal quality is not optimum. Improved recordings can be obtained by repositioning the transducer so that this indicator always shows a solid heart. In the absence of signals of adequate quality this indicator will be permanently off.

The audio volume can be increased by pressing the volume up button marked with the up arrow. Conversely to decrease audio volume press the button marked with the down arrow. In twins mode the audio output is selected for either channel by pressing the US 1/2 button. The selected channel is indicated on the LCD display by the capital US letters. Once a clear fetal heart signal has been located set the volume to the desired level using these controls.

Transducer position should be checked at least half-hourly during labour-monitoring or prolonged NST. When repositioning the transducer, further coupling gel may be required. When repositioning the transducers always ensure that the fetal pulse indicates the optimum signal conditions.

Results will vary from one patient to another, but in all cases good transducer positioning is essential, and this may be aided by the use of a liberal amount of coupling gel.

With the fetus in the vertex presentation, and the mother sitting or supine, the clearest sound will normally be found on the midline below the umbilicus. In the lateral position, clearer sounds may be found with the transducer displaced from the centre line to the upper surface of the abdomen. The clearest signals in breech presentation may be located higher and to one side.





## ***Operating Procedures***

Transducer position which results in sounds with a strong placental or cord signal should be avoided, as these frequently render traces with artifacts.

It is important that a distinct fetal heart sound is present during monitoring for correct function of the unit. Any doubt about fetal variability should be checked by listening to the audible signal, or by an alternative diagnostic technique.

A simple check of the ultrasonic system can be made by holding the transducer against the palm of the hand and stroking the back of the hand at a fixed rate, for example, twice per second. A clear audible signal should be heard and the digital display should show a rate after approximately five seconds. With the printer running this rate will be recorded on the chart.

In the event of HR1 and HR2 traces overlapping or having similar rates the HR2 (US2) trace can be offset by –20bpm by pressing and holding the US½ key. This is reset when the recording session finishes.

### **Uterine Activity Monitoring**

The Toco transducer is used to monitor uterine activity. The transducer plug is colour coded grey for ease of identification. To monitor uterine activity plug the Toco transducer into the grey UA input socket.

The Toco transducer is sealed to prevent the ingress of fluids. NO coupling gel is required for this transducer to operate correctly.

Place the transducer on the centre line over the fundus in a position where the uterus is firm, and secure in place with the stretch belting. Attach belt in the same fashion as with the ultrasound transducer.

Once the transducer is in position, push the Toco Zero button on the front panel to zero the recording. The position of the zero baseline can be set to suit individual preferences. For details of how to change the pre-programmed baseline refer to 'User Configuration'.

### **Fetal Activity**

Fetal activity may be recorded with the assistance of the patient. A hand-held marker switch is provided for this purpose and this is plugged into the socket immediately to the right of the UA input on the front of the unit.

If the patient feels movement of the fetus she may press the switch and this will mark the paper with an arrow in the gap between the HR and UA traces. Alternatively this marker may be used by the midwife to indicate any changes made during the procedure, such as repositioning of the transducers or movement of the patient.

A front panel event marker is also provided, and this marks the trace on the top edge of the HR scale. This can be used where two types of indication are required.





## *Operating Procedures*

### Alarms:

The Fetatrack 310 has built in Bradycardia and Tachycardia alarms. These can be set On or Off in the setup program. The status of the alarms are printed in the center of trace between the UA and FHR traces. When an alarm is activated a down arrow with an "A" is printed at the top of the trace and an audio alarm sounds. Pressing either volume up or down can reset the alarm.

When set to "Level" the Fetatrack 310 monitors the average of the last 30 sec of Heart Rate data and alarms if this falls below the selected numeric value.

When set to "Complex" the Fetatrack 310 monitors the last 3 time periods of 20 sec each of Heart Rate data and alarms if they fall below the selected numeric value and are in a descending rate for Bradycardia or ascending for Tachycardia.

Paper Out will sound a short alarm to draw attention to the monitor, if the paper out store reaches 90% full the Alarm will sound again until cancelled by the user pressing either volume up or volume down.

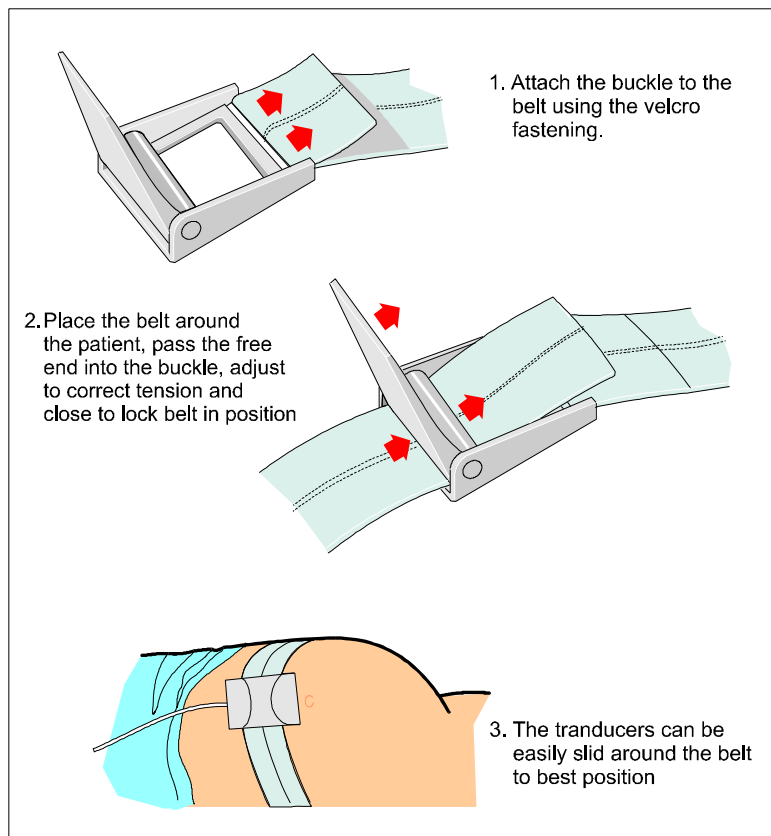




## ***Operating Procedures***

### **Transducer Belts**

Both the ultrasound and contractions transducers are held in position with elastic belting which maintains the active elements in contact with the abdomen. The belts should first be placed around the patient and held in place at the correct tension with the plastic buckles. As the transducers are free to slide on the belt final positioning can be easily achieved. Similarly repositioning of the transducers is made very much simpler.



### **Interpretation**

The following is intended only as a brief guide. For a fuller explanation of the interpretation of chart records, refer to suitable reference books.

During the antepartum period the Non Stress Test (NST) is an accurate means of predicting fetal well-being. The criteria proposed by Schiffrin et al for the interpretation of the NST is summarised.

**Reactive** - accelerations of 15 BPM or more which last for 15 seconds or longer twice in any 10 minute period. These may be accompanied by fetal activity.

**Non-reactive** - evidence of fetal movement during a forty minute period, but without the reactivity indicated above.

**Unsatisfactory** - recording quality too poor to determine the above criteria. Stimulation of the fetus, or repositioning of the transducers may result in an improved recording.

Results from the NST may indicate the requirements to perform other diagnostic checks such as the Contractions Stress Test (CST).





## ***Troubleshooting***

The information in this section will help you to check and correct common operation and system problems. Refer to the troubleshooting hints which deal with your problem. Perform the suggested steps. If the problem is not solved, check once again to make sure that you have used all of the suggested steps to resolve the problem.

Electronic failures and service procedures are not included in this manual, as all servicing of the system must be performed by a qualified service technician. Valuable time however can be saved by documenting the problem .

In general, when you have a problem, check your control settings to be sure that they are in proper operating position. Consult the appropriate section in this manual for specific information on particular controls or operating modes.

### **WARNING:**

Disconnect system from the power source before checking fuses and connections.

Check all connections and fuses. Replace fuses with same type and rating as indicated on the rear panel of the unit.

No display information on LCD

- Verify the system is on and that the fuses are intact.:

Keyboard does not respond

- Reset system by turning off then back on.
- Verify the system is on and that the fuses are intact.

No sound from loudspeaker.

- Verify the system is on and that the fuses are intact.
- Check volume control is set high.
- Check that the correct transducer has been selected.
- Check connection of the transducer.

No FHR information on display or FH trace printed on recorder.

- Check that the correct transducer has been selected and connected to the patient.
- Check connection of the transducer.
- Check for audio FH complex and reposition transducer until clearly heard.

No chart printed .

- Verify the system is on and that the fuses are intact.
- Check that the recorder is turned on.
- Check paper is inserted into the recorder correctly.
- Check recorder door is correctly closed
- Check that paper moves out of the recorder at the correct rate.





## ***Maintenance***

The following are the user preventative maintenance tasks. It is recommended that these be performed on a regular basis at a frequency determined by the usage of the equipment, but not less than once every month.

### **WARNING:**

Before undertaking any of these tasks disconnect the unit from the mains.

#### General

Check all cables, connectors and transducers for damage and repair or replace where necessary. The repair may involve your local service centre, supplier or Ultrasound Technologies Ltd. For advise on any damaged part contact them immediately.

#### Cleaning - Enclosure

Clean the exterior of the system with a soft dry cloth. In the event of stubborn spots, disconnect the system from the power source. Use a soft cloth that has been dampened - not soaked - in a mild detergent solution or isopropyl alcohol. Be sure to keep excess moisture from entering the cabinet via any openings that may be present.

#### Cleaning - Transducers

Use a cloth dampened in a mild detergent solution or isopropyl alcohol to clean the transducer and cable. Remove all traces of the detergent or alcohol by wiping with a cloth dampened in clear water. Never soak the transducer cable or connector.

### **WARNING:**

Transducers must never be exposed to gas or heat sterilization or be left immersed in any liquid for more that a few seconds.





## **Specification**

### **Ultrasound**

|                   |  |
|-------------------|--|
| Frequency         | 1.5 or 2.1 and 1.8 MHz continuous wave |
| Transducer        | Multi element wide angle               |
| Audio Response    | 300 - 1 KHz                            |
| Range             | 50 - 210 bpm                           |
| Power Output      | 5 mW/sq cm max. SATA                   |
| Signal Processing | Software AUTOCORRELATOR                |
| Indicators        | LCD heart rate and pulse indication    |

### **Toco**

|            |   |
|------------|---|
| Transducer | Differential external pressure transducer |
| Response   | 0 - 5 Hz                                  |
| Scale      | 0 - 100                                   |
| Indicators | LCD Toco numeric level indication         |

### **Event Mark**

|                  |               |
|------------------|---------------|
| Hand held        | User operated |
| Unit Front Panel | User operated |

### **Alarms**

|             |                          |
|-------------|--------------------------|
| Bradycardia | Complex and Level alarms |
| Tachycardia | Complex and Level alarms |
| Paper Out   | Short Alarm              |

### **Data Presentation**

Strip chart recorder and alphanumeric display module.

|                   |  |
|-------------------|--|
| Printhead         | 4 inch thermal solid state printhead   |
| Resolution        | 8 dots / mm  |
| Speeds            | 1,2,3,cm/min   |
| Speed accuracy    | Better than 1%   |
| Paper             | Z fold   |
| Paper type        | Black thermal  |
| Paper out storage | 30 mins  |
| Display           | 32 character by 2 line LCD display module  |
| Controls          | 6 control buttons (for Paper Start /Stop, Volume Up, Volume Down, US½, Toco Zero and Event Mark) |
| Indicators        | Green power on/ off  |





## **Specification**

### **Power Supply**

|                  |  |
|------------------|--|
| AC input voltage | 200 - 260 VAC or 100 - 130 VAC (User selected) |
| Frequency        | 46 - 64 Hz                                     |
| Power            | 60VA   |

### **Enclosure**

|          |          |
|----------|----------|
| Material | Aluminum |
|----------|----------|

### **Environmental**

|                               |                |
|-------------------------------|----------------|
| Working temperature           | +10°C to +40°C |
| Relative humidity             | 30% to 75%     |
| Storage/Transport temperature | -10°C to +70°C |

### **Safety**

|                        |                                |
|------------------------|--------------------------------|
| Unit                   | Designed to BS EN60601-1-1990. |
| Electrical Designation | Class 1 Type B                 |

### **Computer interface**

|               |                             |
|---------------|-----------------------------|
| Transfer      | 3 wire RS232                |
| Data Rate     | 9600 baud                   |
| Data Standard | 8 bits no parity 1 stop bit |
| Data Format   | UltraTec Comms Standard     |

### **The following Consumables are available for use with the FETATRACK 310**

Belt / Buckle set (10 belts / 2 Buckles per pack)  
Chart pack (10 per pack))  
Power Cord  
Coupling gel (0.25ltr) (12 per box)

**This Equipment complies with the essential requirements of the European Council Directive. 93/42/EEC**





**Electromagnetic Compatibility****Guidelines for Identifying and resolving adverse EMC conditions****Emissions**

Care has been taken through the design and manufacturing processes to minimise the EM emissions that may be produced by this equipment. However, in the unlikely event that the unit causes an EM disturbance to adjacent equipment, we suggest that the procedure is carried out 'out of range' of the affected equipment.

**Immunity**

If the user has any doubt regarding the unit's EM immunity during routine operation, we suggest that the source of EM disturbance is identified and its emissions reduced.

If the user has any doubt regarding the identification and resolution of adverse EM conditions, they may contact Ultrasound Technologies Ltd to seek advice

**EMC Testing**

During conformity testing the Fetatrack 310 was subjected to International Standard EMC tests. During the majority of these tests no non conformances were observed.

During EN60601-1-1:2001 testing the FetaTrack 310 was shown to be susceptible to the following tests.

|  |   |   |   |
|--|---|---|---|
| Conductive disturbance induced by applied RF field | Test applied a 3Vrms RF magnetic field to transducer cables with a 2Hz modulation.                                    | Effect was a displayed rate of 115 to 125 bpm at each harmonic and sub harmonic of the transducer frequency. No disturbance was detected at other frequencies | Applied test signal is very high for high sensitivity electronics and non applied transducers. With correctly applied transducers interference from in band RF signals is unlikely. |
| Radiated RF  | Test applied: 3V/m 80Mz to 2.5GHz   | Effect was a disturbance to the UA transducer causing a static UA reading of up to 9 units  | Normal operation is unaffected and the static reading can be cancelled by pressing the toco zero button   |
| Electrical fast transients and bursts              | Test applied: +/-2KV AC power, +/-1KV Signal Cables   | Effect was a FHR reading of 198 BPM .   | Normal mains power is unlikely to cause such a transient / burst. Displayed rate is unlikely to occur when transducers are connected to a patient.                                  |
| Electro Static Discharge                           | Test applied: +/-2KV, +/-4Kv, +/-8KV Air Discharge, +/-2KV, +/-4KV, +/-6KV Contact Discharge. Repetition Rate 1second | Effect was a FHR reading of 58 BPM .  | Unit should be used in a low static environment. Displayed rate is unlikely to occur when transducers are connected to a patient.   |
| Surge  | Test applied: +/-0.5KV, +/-1KV, +/-2KV AC power line to ground, +/-0.5KV, +/-1KV, +/-6KV AC power line to line        | Effect was a FHR reading of 58 BPM .  | Normal mains power is unlikely to cause such a surge. Displayed rate is unlikely to occur when transducers are connected to a patient.  |



## **Waste Electrical and Electronic Equipment (WEEE) Directive (2002/96/EC)**

There is an increasing interest in the proper disposal of used electronic equipment. The European Union (EU) has developed the WEEE (Waste Electrical and Electronic Equipment) Directive to ensure that systems for collection, treatment and recycling of electronic waste will be in place throughout the European Union.

### **Ultrasound Technologies Position with regard to the WEEE Directive**

Product recycling is nothing new and Ultrasound Technologies have implemented processes in each member state where the company has a presence. Ultrasound Technologies will comply with the provisions of the WEEE Directive and national implementing legislation.

### **Instructions for Disposal of Waste Equipment by Users in Private Households**



This symbol on the product or on its packaging indicates that this product must not be disposed of with your other household waste. Instead, it is your responsibility to dispose of your waste equipment by handing it over to a designated collection point for the recycling of waste electrical and electronic equipment. The separate collection and recycling of your waste equipment at the time of disposal will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment. For more information about where you can drop off your waste equipment for recycling, please contact your local waste disposal authority, your household waste disposal service or the supplier where you purchased the product.

As a producer of electronic devices, Ultrasound Technologies will provide for the financing of the treatment and recycling of waste returned through these designated collection points in accordance with local requirements.

### **Instructions for Disposal of Waste Equipment by Commercial Users**

For users of Ultrasound Technologies equipment, other than private households, Ultrasound Technologies will provide free recycling of equivalent medical electronic equipment once a customer has returned the equipment to Ultrasound Technologies, with all transport and importation costs paid, and where a replacement product is being supplied by Ultrasound Technologies. Where a replacement product is not being supplied, recycling services may be provided on request at additional cost.

### **RoHS**

The RoHS (Restriction of Hazardous Substances) directive (2002/95/EC), compliments the WEEE Directive by banning the presence of specific hazardous substances in the products at the point of manufacture.

Ultrasound Technologies is a manufacturer of Medical Devices and is currently exempt from this directive.

However at Ultrasound Technologies we take our responsibilities to the environment very seriously and currently 99% of our entire manufacturing process and parts meet the RoHS directive and full compliance is expected within 2007.